Special 510(k) Summary

1. COMPANY INFORMATION

   Cincinnati Sub-Zero Products, Inc.
   12011 Mosteller Road
   Cincinnati, Ohio 45241-1528
   Telephone; (513) 772-8810
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2. CONTACT INFORMATION

   Steve Berke
   President and CEO
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3. DATE PREPARED: June 3, 2012

4. DEVICE TRADE NAME: WarmAir® Model 135 Hyperthermia System including blankets

5. COMMON NAME: Temperature Management System

6. CLASSIFICATION NAME: System, Thermal Regulating

7. CLASSIFICATION REGULATION: 21 CFR 870.5900

8. CLASSIFICATION PRODUCT CODE: DWJ (Thermal Regulating System)

9. PANEL: Cardiovascular

10. DEVICE CLASSIFICATION: Class II No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act

11. IDENTIFICATION OF PREDICATE:
    a. WarmAir® Model 135 Hyperthermia System including blankets (K101148)

DEVICE DESCRIPTION

The WarmAir 135 Hyperthermia System is a patient temperature management device which provides forced air warmed by the controller to a blanket that is placed over or under adult, pediatric or neonatal patients in order to warm them. The heated air is blown

through connecting flexible hose to a disposable blanket to provide patient therapy by the means of warmed air.

The system can be used in long-term care facilities, surgical facilities, hospitals including the Post-anesthesia Care Unit (PACU), Intensive Care Unit (ICU), Surgical Intensive Care Unit (SICU), Emergency Room (ER), Operating Room (OR), recovery room, medical and surgical floors, emergency department, or any other department or hospital facility requiring patient temperature management.

DESCRIPTION OF THE CHANGES TO THE DEVICE

The predicate WarmAir Model 135 System included a variety of blankets in various sizes and shapes and was cleared in K101148. This submission is to add a modified blanket to the family of WarmAir 135 blankets. The modified blanket is manufactured from the same materials using the same manufacturing methods as the already cleared blankets. The differences are that the modified blanket is provided sterile, differs in size from other blankets, and includes a flap to allow access to the groin area of the patient.

INTENDED USE

The WarmAir 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient's temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric, or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

COMPLETION OF DESIGN CONTROL ACTIVITIES

The changes to the blanket were evaluated under design controls and met the same criteria as non-sterile blankets. Testing showed the sterile blanket meets the specification for maximum temperature delivered to the patient (per ASTM F-2196) post sterilization.

SUBSTANTIAL EQUIVALENCE

The modified device has the same intended use as the predicates and similar technological characteristics that do not raise different types of questions of safety and effectiveness and the modified device is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 3 2012

Cincinnati Sub-Zero Products, Inc.
c/o Mr. Steven J. Berke
President and Chief Executive Officer
12011 Mosteller Road
Cincinnati, OH 45241-1528

Re: K121669
WarmAir®, Model 135 Hyperthermia System (Controller and Blankets)
Regulation Number: 21 CFR 870.5900
Regulation Name: System, Thermal Regulating
Regulatory Class: Class II
Product Code: DWJ
Dated: June 4, 2012
Received: June 6, 2012

Dear Mr. Berke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121669

Device Name: Warm Air® Model 135 and Blankets

Indications for Use:

The WarmAir® 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient's temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121669

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(Posted November 13, 2003)